UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	No. 02 C 5129
v.	)	
	)	Judge Kennelly
EASTERN SEAFOOD, INC., *et al*.,	)	
	)	
Defendants.	)	

UNITED STATES' OPPOSITION TO DEFENDANTS'
PETITION TO VACATE CONSENT DECREE OF PERMANENT INJUNCTION

Introduction

The court should deny defendants Eastern Seafood, Inc. and Mario Falco's motion to vacate the Consent Decree of *Permanent* Injunction to which they *agreed* in 2002. Food and Drug Administration investigators have documented violations of the consent decree as recently as last year, during their April 2014 inspection of Eastern Seafood. Among other things, investigators found an employee of defendants creating documentation that should have been prepared at or near the time of the events the documents recorded. They observed a mold-like substance on the ceiling above ingredients used in food processing and on a tarp covering food processing equipment. They saw an employee handling food without washing or sanitizing his hands, other employees walking through the food processing area and storage cooler without proper hair covering, and condensate dripping from a condenser onto uncovered raw fish. They also saw old, food-like residue on the blade of a saw used to cut fish products, even though the defendants' records represented that the equipment had been "cleaned and sanitized" to a "satisfactory level." These and other documented violations, combined with comments made

during the inspection by Defendant Falco, Eastern Seafood's president, that the consent decree "means nothing" to him and was "garbage," amply demonstrate that the consent decree and the oversight it provides remain necessary to ensure that the defendants comply with the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Background

I. Regulation of Processors of Fish and Fishery Products

Defendants Eastern Seafood, Inc. and Marion Falco process fish and fishery products. As such, they are required to conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each product they process, and to identify the preventive measures that can be applied to control those hazards. 21 C.F.R. § 123.6(a). If they identify that any food safety hazards are likely to occur, defendants are required to develop, implement, and verify appropriate plans, referred to as Hazard Analysis and Critical Control Point ("HACCP") plans, specific to each of their products. 21 C.F.R. § 123.6(b). Each HACCP plan must include appropriate steps related to monitoring, verification, recordkeeping, corrective actions, and sanitization-control procedures to ensure the plan is effectively implemented. 21 C.F.R. §§ 123.6–123.11. By developing, implementing, and verifying adequate written HACCP plans specific to each of their products, fish and fishery products processors control the health risks associated with these products. *See generally* Declaration of Jane Cluster ("Cluster Decl.") ¶ 4, attached as Exhibit 1.

Food is adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4), if it "has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Fish and fishery products processed without adequate written HACCP plans

are adulterated as a matter of law under 21 U.S.C. § 342(a)(4). 21 C.F.R. § 123.6(g); *see also Blue Ribbon Smoked Fish*, 179 F. Supp. 2d 30, 35 (E.D.N.Y. 2001) ("Because the defendants' HACCP plans are inadequate and do not comply with the FDA regulations, the food [defendant] processes pursuant to them is adulterated as a matter of law, as defined by Section 342(a)(4) of the FDCA."), *aff'd in relevant part*, 56 Fed. Appx. 542 (2003); *see also* Cluster Decl., Exhibit 1, ¶ 5.

II. Procedural History

In July 2002, the United States filed a complaint for injunction, alleging that defendants violated the Act, 21 U.S.C. § 331(k), by causing articles of food, namely scrombrotoxin fish products, to become adulterated while held for sale after shipment in interstate commerce. Complaint ¶ 1. Defendants' fish products were adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4), in that they had been prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health. *Id.* ¶ 6. Specifically, because defendants failed to develop and implement an adequate HACCP plan for their fresh scrombrotoxin fish products as required by FDA's regulations found at 21 C.F.R. Part 123, the food they produced was adulterated within the meaning of 21 U.S.C. § 342(a)(4). *Id.* ¶ 9.

In August 2002, this court entered a Consent Decree of Permanent Injunction that, among other things, required defendants to "have in place and implement[] a HACCP plan that contains an ongoing scrombrotoxin control program, and ongoing verification procedures in the HACCP plan that ensure that the plan continuously controls the scrombrotoxin hazard and that the plan is being consistently followed." Decree ¶ V. The decree further restrained and enjoined defendants "from doing or causing to be done, directly or indirectly, any act that violates 21

U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) after shipment in interstate commerce." *Id.* ¶ VIII.

III. Evidence of Defendants' Violative Conduct since 2009

During FDA's most recent inspection of Eastern Seafood conducted on March 31 and April 2, 2014, FDA investigators observed and documented numerous significant HACCP violations, including but not limited to, the following:

(1) failure to record information in defendants' records at the time observed, in violation of 21 C.F.R. § 123.9(a). The fact that defendants' employee was observed creating records during the inspection that should have been documented contemporaneously (more than one month before) is extremely troubling and calls into question all of defendants' recordkeeping practices;

(2) failure to implement monitoring and recordkeeping procedures listed in defendants' HACCP plan, in violation of 21 C.F.R. § 123.6(b);

(3) failure to calibrate process-monitoring equipment, in violation of 21 C.F.R. 123.8(a)(2)(ii);

(4) failure to include an adequate corrective action plan in accordance with 21 C.F.R. § 123.7(b) to prevent potentially unsafe food from entering commerce when a HACCP deviation occurs, in violation of 21 C.F.R. § 123.6(c)(5);

(5) failure to monitor sanitation conditions and practices with sufficient frequency to ensure conformance with current good manufacturing practice, including the prevention of cross-contamination from insanitary objects and the protection of food, food packaging material, and food contact surfaces from adulteration, in violation of 21 C.F.R. § 123.11(b); and

(6) failure to accurately document sanitization practices, in violation of 21 C.F.R. § 123.11(c).

See Declaration of Nicholas Lyons ("Lyons Decl.) ¶ 8, attached here as Exhibit 2.

During the 2014 inspection, among other things, investigators found an employee of defendants creating documentation that should have been prepared at or near the time of the events the documents recorded. *See* Exhibit 3, Declaration of FDA Investigator Patrick Gainer at Exhibit A, Observation 1. They observed a mold-like substance on the ceiling above ingredients used in food processing and on a tarp covering food processing equipment. *Id.* Observation 5. They saw an employee handling food without washing or sanitizing his hands, other employees walking through the food processing area and storage cooler without proper hair covering, and condensate dripping from a condenser onto uncovered raw fish. *Id.* They also saw old, food-like residue on the blade of a saw used to cut fish products, even though the defendants' records represented that the equipment had been "cleaned and sanitized" to a "satisfactory level." *Id.* Observation 6. Additionally, when the lead investigator handed Falco a copy of the consent decree pursuant to which the inspection was being conducted, Falco told the FDA investigators that the decree "means nothing" to him and was "garbage." Lyons Decl., Exhibit 2, at ¶ 10; Gainer Decl., Exhibit 3, at ¶ 4. At the conclusion of the inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA 483") to defendant Falco. Lyons Decl., Exhibit 2, at ¶ 11; Gainer Decl., Exhibit 3, Ex. A. . These observations constitute violations of the Act and the HACCP regulations. Cluster Decl., Exhibit 1, ¶ 6.[1]

[1] FDA began an inspection of Eastern on April 7, 2015, approximately one year since the last inspection. This inspection was planned before the defendants filed their Motion to Vacate the Decree. Lyons Decl. ¶ 18.

During FDA's inspection of Eastern Seafood conducted between November 18 and December 8, 2009, investigators identified numerous significant HACCP violations, many of which were the same as those identified during FDA's 2014 inspection, as follows: (1) failure to develop a written HACCP plan that controls a food safety hazard that is reasonably likely to occur, in violation of 21 C.F.R. § 123.6(b); (2) failure to establish and implement any written verification procedures to ensure that imported fishery products are processed in compliance with HACCP regulations, in violation of 21 C.F.R. § 123.12(a)(2); (3) failure to list adequate monitoring frequencies to prevent the food safety hazard of *Clostridium botulinum* growth and toxin, in violation of 21 C.F.R. § 123.6(c)(4); (4) failure to include an adequate corrective action plan in accordance with 21 C.F.R. § 123.7(b) to prevent potentially unsafe food from entering commerce when a HACCP deviation occurs, in violation of 21 C.F.R. § 123.6(c)(5); (5) failure to calibrate process monitoring equipment, in violation of 21 C.F.R. § 123.8(a)(2)(ii); (6) failure to adequately verify the implementation of their HACCP plan and to list adequate verification procedures to ensure that their HACCP plans are adequate and effectively implemented, in violation of 21 C.F.R. §§ 123.6(c)(6) and 123.8(a)(2); (7) failure to accurately document sanitization practices, in violation of 21 C.F.R. § 123.11(c); and (8) failure to monitor sanitation conditions and practices with sufficient frequency to assure conformance with current good manufacturing practice, in violation of 21 C.F.R § 123.11(b). Lyons Decl. ¶ 14; Cluster Decl. ¶ 7.

At the conclusion of the 2009 inspection, the FDA investigators issued a Form FDA 483 to Defendant Falco, and discussed the violative conditions with him. Lyons Decl., Exhibit 2,

¶ 15 and Exhibit C. By letter dated January 21, 2010, FDA again notified defendants that they were not complying with the Act, its implementing regulations, or the decree. *Id.* ¶ 17.[2]

Argument

I. Defendants' Failure to Comply with the Act and the Decree

As discussed above, FDA's investigators have observed and documented defendants' significant deviations from FDA's HACCP regulations, most recently in April 2014 and previously in 2009. These inspections demonstrate that defendants have repeatedly failed to establish and implement HACCP plans that include adequate monitoring, verification, recordkeeping, corrective action plans, and sanitization control procedures. Therefore, because defendants' HACCP plans do not comply with 21 C.F.R. Part 123, the food defendants' process pursuant to them is adulterated as a matter of law under 21 U.S.C. § 342(a)(4). [3]

Defendants' argument that the decree should be vacated because they have not been "cited with violations" since 2002 (Defs' Mot. at 2) betrays a misunderstanding of the law and FDA's regulatory processes. FDA does not cite processors with violations during an inspection. Rather, at the conclusion of an inspection, FDA investigators issue to the firm's most responsible person a Form FDA 483 documenting their inspectional observations and they discuss those

[2] FDA inspected Eastern Seafood in 2010 and 2011 and did not observe any significant violations of the decree or the Act. Lyons Decl. ¶ 13.

[3] To the extent that defendants attempt to narrow the scope of the decree to cover only scrombroid toxin fish products, we note that paragraph VIII restrains defendants from introducing *any food* into interstate commerce that is adulterated under 21 U.S.C. § 342(a)(4), which includes any fish or fishery products processed without adequate HACCP plans. Further, although FDA investigators did not observe defendants processing any scrombroid toxin fish during the 2014 inspection, they noted that defendants' "Weekly Restaurant Price List" includes mahi-mahi (a scrombroid toxin fish) as available for sale. Lyons Decl. ¶ 9. Most importantly, although the HACCP plans FDA reviewed during the 2014 inspection were not for scrobroid toxin fish products, the violations observed during that inspection reveal that defendants are unable or unwilling to comply with the requirements of 21 C.F.R. Part 123 generally.

observations with that person. Lyons Decl. ¶ 6. The investigators then draft an Establishment Inspection Report which, along with the Form FDA 483, is reviewed by compliance officers in FDA's district office and/or the relevant product center. *Id.* ¶ 7. The Agency then assigns the inspection a classification that reflects the compliance status of the establishment at the time of the inspection taking into account the investigators' factual observations and the input of other agency officials with expertise in the subject-matter area. *Id.* Here, FDA classified the 2014 and 2009 inspections of Eastern Seafood as "Official Action Indicated," which means that significant objectionable conditions or practices were found and regulatory action was warranted to address the firm's lack of compliance with the Act and/or its regulations. *Id.* ¶¶ 12, 16.

The fact that FDA has not found actual contamination at defendants' facility or in their fish products (*see* Defs' Mot. at 2) is legally irrelevant. It is well established that actual contamination need not be shown in order for food to be deemed adulterated under 21 U.S.C. § 342(a)(4). *See United States v. H. B. Gregory Co.*, 502 F.2d 700, 704-05 (7th Cir. 1974) ("It is clear that the congressional intent is to make it a criminal offense for a person to . . . hold food under such insanitary conditions that it *may* become contaminated. It is not necessary that it actually become contaminated. . . . The statute is designed to prevent adulterations 'in their incipiency' by condemning insanitary conditions which may result in contamination.") (internal quotes omitted) (emphasis added).

Because defendants have failed to develop, implement, and verify adequate written HACCP plans, there is an increased likelihood of food safety hazards and consequently, increasing risk of injury or illness for consumers. *See* Cluster Decl. ¶ 8. The intent of the decree was to ensure that defendants complied with the law to best protect the public from adulterated

food. Contrary to defendants' assertion that the "intent" of the decree has been achieved (Def.s' Mot. at 2), there is an ongoing need for this decree to remain in effect in light of defendants' ongoing failure to comply with the HACCP regulations. Separately, defendants' apparent disregard of the decree, *see* Lyons Decl. ¶ 10, is further evidence of the need for this court to maintain jurisdiction over defendants and for the decree's requirements to be in full force.

Finally, defendants assert that they should be relieved of the decree because they claim to have satisfied FDA's typical "sunset provision" which, they argue, is "virtually always 5 years" (Defs' Mot. at 2). But this decree is an order of *permanent* injunction and does not contain any sunset provision. And, even if it had included such a provision, defendants could not avail themselves of it because they have not maintained compliance for five years. *See* FDA's Regulatory Procedures Manual ("RPM") § 6-2-16 (available at (http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176734.htm#6-2-16_-_Vacating_Injunctions) (explaining that FDA does not ordinarily oppose a motion to vacate a decree *if* (a) the agency has recent evidence that the defendant is in compliance with the Act, applicable regulations, and the decree; (b) *the defendant has remained in continuous compliance with the Act, applicable regulations, and the decree for a period of five years*; and (c) the defendant has given FDA an opportunity to consider whether to object to the motion). In this case, because defendants have not been in continuous compliance with the Act or the decree for the past five years, FDA objects to this motion.[4]

[4] Defendants did not give FDA an opportunity to consider whether to object to a motion to vacate prior to filing their motion with the court. Accordingly, none of the conditions identified in the RPM are met here.

II. Defendants Do Not Satisfy Requirements for Vacating a Court Order

Although defendants do not cite any law in support of their motion, the relief they seek is governed by Rule 60 of the Federal Rules of Civil Procedure. *See Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 378 (1992) (explaining that a consent decree "is an agreement that the parties desire and expect will be reflected in, and be enforceable as, a judicial decree that is subject to the rules generally applicable to other judgments and decrees."); *see also United States v. Krilich*, 303 F.3d 784, 789 (7th Cir. 2002). Rule 60(b) provides for relief from a final judgment for the following reasons:

> (1) mistake, inadvertence, surprise, or excusable neglect;
> (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
> (3) fraud . . . , misrepresentation, or misconduct by an opposing party;
> (4) the judgment is void;
> (5) the judgment has been satisfied, released or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
> (6) any other reason that justifies relief.

Fed. R. Civ. P. 60(b).

"Relief under Rule 60(b) is an extraordinary remedy granted only in exceptional circumstances." *Nelson v. Napolitano*, 657 F.3d 586, 589 (7th Cir. 2011). Here, defendants do not argue that any of the conditions supporting vacating a decree exist. However, giving defendants the benefit of the doubt, their motion could be construed as arguing that the decree should be vacated under Rule 60(b)(5) because applying it "prospectively is no longer equitable." *See* Defs' Mot. at 2 (arguing that "to continue to hold defendants beholden to the order is unnecessary and oppressive" and "it would be fair, equitable, and just, to vacate the order"). Defendants cannot make such a showing, however.

To satisfy the Rule 60(b)(5) standard, the party seeking to modify the consent decree "'bears the burden of establishing that a significant change in circumstances warrants revision of the decree.'" *O'Sullivan v. City of Chicago*, 396 F.3d 843, 861 (7th Cir. 2005) (quoting *Rufo*, 502 U.S. at 383). The moving party may meet this burden "'by showing a significant change either in factual conditions or in law.'" *O'Sullivan*, 396 F.3d at 861 (quoting *Rufo*, 502 U.S. at 384). If the moving party meets this initial burden, "a district a court should consider whether the proposed modification is 'suitably tailored to the changed circumstances.'" *O'Sullivan*, 396 F.3d at 861 (quoting *Rufo*, 502 U.S. at 383).

Defendants have made no showing of a significant change in either the factual circumstances or the law. The fact that continuing to comply with the decree's requirements is inconvenient is an insufficient ground for vacating the decree. *See Rufo*, 502 U.S. at 383 (an assertion that it is "no longer convenient to live with the terms of a consent decree" is insufficient). Any financial burdens or other obligations required by the decree were or should have been anticipated by defendants at the time they voluntarily (and with counsel) signed the decree. *Rufo*, 502 U.S. at 384 ("Ordinarily . . . modification should not be granted where a parties relies upon events that actually were anticipated at the time it entered into a decree."). Lastly, the Supreme Court has stated that a court may consider vacating a decree when dissolution will benefit the public. *See Rufo*, 502 U.S. at 384. Here, in light of defendants' recent non-compliance with the decree and the Act, vacating the decree would be contrary to the public interest; indeed, it would increase the likelihood that the public would be exposed to Defendants' adulterated products.

None of the other grounds for relief in Rule 60(b) are either alleged or available to defendants. Defendants do not raise either mistake, inadvertence, surprise, or excusable neglect (Rule 60(b)(1)), newly discovered evidence (Rule 60(b)(2)), or fraud or misrepresentation (Rule 60(b)(3)).[5] Because there is no reason to believe that the court lacked jurisdiction or did not follow due process, the decree is not void under Rule 60(b)(4). *See United States v. Krilich*, 152 F. Supp. 2d 983, 991 (N.D. Ill. 2001) ("A judgment is void if it is without subject matter jurisdiction, there was no personal jurisdiction over a party, or the judgment was entered without due process of law.").

Defendants also are not entitled to relief under Rule 60(d)(6)'s "catch-all" provision. Relief from a decree under this provision "is warranted only upon a showing of *extraordinary circumstances* that create a substantial danger that the underlying judgment was unjust." *Margoles v. Johns*, 798 F.2d 1069, 1073 (7th Cir. 1986) (emphasis added). Defendants have not argued that any "extraordinary circumstances" support their motion. Rather, this case involves nothing more than Defendant Falco attempting to avoid the obligations of a resolution that he entered into voluntarily and violated as recently as one year ago. Rule 60(b) thus does not provide grounds for relief from the decree.

[5] Relief under Rule 60(b)(1), (2), and (3) is also not available to defendants because their motion is untimely. *See* Fed. R. Civ. P. 60(c) ("A motion under Rule 60(b) must be made within a reasonable time — and for reasons (1), (2), and (3) no more than a year after entry of the judgment or order of the date of the proceeding.").

Conclusion

For the foregoing reasons, the court should deny the defendants' motion for relief from the decree..

Respectfully submitted,

ZACHARY T. FARDON
United States Attorney

By: s/ Donald R. Lorenzen
DONALD R. LORENZEN
Assistant United States Attorney
219 South Dearborn Street
Chicago, Illinois 60604
(312) 353-5330
donald.lorenzen@usdoj.gov

Of counsel:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel, Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

MICHELE SVONKIN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 32, Room 4308
Silver Spring, Maryland 20993-002

Dated: April 10, 2015